

### REMARKS

In the Office Action dated March 13, 2006, the Examiner has rejected claims 16-21, 23-27, 29, 30 and 32-36, and the Examiner has objected to claims 22 and 31 as further discussed below. Applicants believe that the analysis and response presented herein shows that the claims are in condition for allowance. In view of the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

#### The Information Disclosure Statement Filed 12/29/05

An Information Disclosure Statement (IDS) previously filed on 12/29/05 cited numerous U.S. and Foreign Patent Documents. The Examiner states in the Office Action that the IDS filed 12/29/05 did not include a legible copy of each cited foreign patent document as required by 37 C.F.R. 1.98(a)(2). The Applicant stated in the IDS that the foreign patent documents cited therein were previously submitted to the Patent Office in an IDS filed 2/27/02 in prior U.S. Patent Application Serial No. 09/978,932, filed October 16, 2001, of which the present application claims priority under 35 U.S.C. §120. As per 37 CFR §1.98(d), the foreign patent documents were not provided in the IDS filed 12/29/05. For the Examiner's convenience, the Applicant is attaching hereto legible copies of each foreign patent document cited in the IDS filed 12/29/05 (French Patent No. 2 758 971, dated 8/1998; French Patent No. 2 763 828, dated 12/1998; and German Patent Application Publication No. 197 20 782 A1, dated 11/1998). The Applicant respectfully requests consideration of these references and requests for these references to be indicated as considered by the Examiner.

#### Allowable Subject Matter

Claims 22 and 31 were objected to as being dependent upon rejected base claims. Applicant has not amended the rejected base claims and instead offers further arguments as to the patentability of independent claims 16 and 30. Applicant notes, however, that consistent with the previous Office Action's conditional allowance of claims 22 and 31 (i.e., allowable if rewritten in independent form), new independent claims 37 and 43 have been added to in this Amendment consistent with rewriting claims 22 and 31 in independent form.

The rejections under 35 U.S.C. § 102

Claims 34-36 were rejected under 35 USC §102(b) as being allegedly anticipated by U.S. Patent No. 5,616,142 to Yuan et al. Regarding independent claims 34 and 36, both claims recite an "upper portion having a substantially flat upper surface." The ordinary meaning of the term 'flat' means 'level and horizontal,' or, 'not curved inward or outward.' *MSN Encarta*, July 20, 2006. 'Flat' does not include surfaces that cannot be found in a plane, such as the top surface shown on the cover sheet of Yuan, as well as in at least FIGS. 1, 2, 4c, and 5. Likewise, FIGS. 4a and 4b suggest a curved surface in that one side of holes 12'' and 22'' can be seen in the figures, indicating a view biased to one side of the hole centerline. Additionally, it is believed that Yuan fails to explicitly disclose a flat surface in the specification.

On at least these grounds, claims 34 and 36 are allowable over the Yuan reference, because Yuan fails to disclose a "flat upper surface." Applicants respectfully request withdrawal of the rejection of claims 34 and 36 over Yuan.

Claim 35 depends from claim 34 and therefore includes all of the elements of claim 34. Claim 35 is allowable over the cited reference for at least the reasons cited above with respect to claim 34. Applicants respectfully request withdrawal of the rejection of claims 34 – 36.

Claims 30, 32, and 33 were rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent No. 2, 511,051 to Dzus. Regarding independent claim 30, claim 30 recites, among other things, a "hole having at least one tapered section." The ordinary meaning of the term 'tapered' means a 'gradual narrowing in the shape of something.' *MSN Encarta*, July 20, 2006. The Office Action alleges that the dimple disclosed in Dzus is the same thing as a "hole having a tapered section." However, a 'dimple' means an indented, hollowed, or depressed area. *MSN Encarta*, July 20, 2006. Comparing, for the moment, the term "dimple" to "taper," a gradual narrowing in the shape of something (taper) is not the same thing as an indented, hollowed, or depressed area (dimple). For example, an elongate dinner candle can have an elegantly shaped contour that tapers from a relatively modest base to a narrow tip, but the candle can also have a number of inelegant depressions, such as dimples, in its surface. Other depressions might also be formed in the surface of the candle. The two terms, therefore, are mutually exclusive as they refer to different characteristics of a given object.

The clip in Dzus has a depression that is referred to as a dimple, and the Office Action likewise uses the same language. It will be appreciated, therefore, that the depression in Dzus is properly called a dimple, and not a taper, and therefore, Dzus fails to anticipate claim 30. On at least these grounds, claim 30 is allowable over the Dzus reference. Applicants respectfully request withdrawal of the rejection of claim 30.

Claims 32 and 33 depend from claim 30 and therefore include all of the elements of claim 30. Claims 32 and 33 are allowable over the cited reference for at least the reasons cited above with respect to claim 30. Additionally, claim 32 is allowable on its own merit because Dzus does not disclose a body having an octagonal shape. Dzus discloses, on the other hand, a

substantially circular clip, with a pair of opposed, depending prongs that accent the substantially circular clip with squared edges, as best seen in FIG. 8.

Additionally, claim 33 is allowable on its own merit because Dzus does not disclose a body that has a lower surface that is convex. Rather, Dzus discloses a clip with a concave lower surface. Claims 32 and 33, therefore, are allowable over the cited reference for at least the reasons recited above. Applicants respectfully request withdrawal of the rejection of claims 30, 32, and 33.

#### The rejections under 35 U.S.C. § 103

Claims 16-21 were rejected under 35 USC §103(a) as being allegedly unpatentable over U.S. Patent No. 5,616,142 to Yuan et al. in view of U.S. Patent No. 6,305,135 to Baccelli. Regarding independent claim 16, Applicants submit that a *prima facie* case of obviousness cannot be established because there is no teaching, suggestion or motivation to arrive at the combination of features recited in claim 16. The Office Action purports to provide motivation based on conclusory statements of generalized advantages by alleging that “[i]t would have been obvious to one having ordinary skill in the art to have made the plate 10 of Yuan et al flat which is cheaper and easier to produce and further give the surgeon the choice of which shape best fits the patient.” Pg. 5 [emphasis added]. It is believed that neither the Yuan reference nor the Baccelli reference explicitly disclose the motivation alleged in the Office Action, specifically whether Yuan and/or Baccelli suggests the ease and/or low cost of manufacturing a flat plate. Furthermore, no citation is provided in the Office Action that identifies where such motivation exists. By failing to identify where the motivation can be found, the Office Action fails to

clearly explain the desirability or the feasibility of modifying the Yuan reference in view of Baccelli.

It appears that the Office Action is possibly using impermissible hindsight to provide the requisite motivation; or, perhaps the Office Action is relying on facts within the personal knowledge of the Examiner. If, on further review, the Office Action indeed relies on such facts, Applicants hereby request an affidavit of the Examiner, pursuant to 37 C.F.R. 1.104(d)(2), to specifically describe such personal knowledge in order to better develop a full record on which the prosecution can advance.

In addition to the above, Baccelli explicitly teaches away from the device in Yuan by disclosing a number of disadvantages in the Yuan reference. See col. 1, lines 24 – 51. Specifically, Baccelli teaches that the plate comprised of the two sliding parts in Yuan “has the disadvantage that there is a risk of play between the two parts, and this play can encourage accidental loosening of the screws.” Baccelli also teaches that the two sliding parts in Yuan are “[incapable] of maintaining a desired spacing between the two vertebrae in the longitudinal direction of the spine, so that the initial compression of the bone graft can be adversely affected, with, as a consequence, poor quality or speed of fusion, or even completely defective fusion.” Specifically, Baccelli discloses that its invention overcomes these disadvantages by making an implant that is “substantially simpler to fit and in which it is possible to use a plate made up of two sliding elements in order to establish and maintain a compression of bone grafts which have been introduced between two vertebrae on which the implant is to be anchored.” None of these statements endorse the combination alleged in the Office Action. In fact, as will be appreciated, Baccelli teaches away from Yuan by offering a solution to the disadvantages in Yuan, and in so doing, implicitly suggests that the Yuan device would be inadequate for the uses contemplated in

Baccelli. Therefore, the 103 rejection should be withdrawn because Baccelli cannot properly be combined with Yuan.

In addition to the reasons above, claim 16 recites, among other things, an “upper portion having a substantially flat upper surface.” The ordinary meaning of the term ‘flat’ means ‘level and horizontal,’ or, ‘not curved inward or outward.’ *MSN Encarta*, July 20, 2006. The term ‘flat’ cannot include surfaces that are curved or that otherwise that cannot be found in a plane, such as the top surface shown on the cover sheet of Yuan, as well as in at least FIGS. 1, 2, 4c, and 5. In addition to these figures, FIGS. 4a and 4b suggest a curved surface in that one side of holes 12” and 22” can be seen in the figures; if the surface were not curved, the sides of holes 12” and 22” would either not be seen (as in an isometric view), or would be equally seen around the entire circumference of the holes (as in a perspective view). Based upon the definition and the figures disclosed, Yuan fails to explicitly disclose a flat surface in the specification; in particular, Yuan fails to disclose a “flat upper surface.”

Similar to Yuan, Baccelli also fails to disclose a ‘flat’ upper surface. In particular, Baccelli discloses two plate elements 10 that are slidably joined thereby creating an irregular upper surface as can best be seen on the cover sheet of Baccelli as well as in FIGS. 1, 2, 3, 5, 6, 7, and 8. The irregular upper surface is not a ‘level and horizontal’ surface because it is composed of multiple steps and discontinuities. Like Yuan, Baccelli too fails to disclose a ‘flat’ upper surface.

Applicants note that to establish a *prima facie* case of obviousness, three basic criteria must be met including the requirement that all claim limitations must be taught or suggested. In particular, the MPEP states that:

[f]irst, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. MPEP 706.02(j) [emphasis added]; *See also* MPEP 2143.01 – 2143.03.

Neither Yuan nor Baccelli disclose a “flat upper surface” and as such, the *prima facie* case of obviousness cannot be made. Applicants respectfully request withdrawal of the rejection of claim 16 over Yuan and Baccelli.

Claims 17 - 21 depend from claim 16 and therefore include all of the elements of claim 16. Claims 17 - 21 are allowable over the cited reference for at least the reasons cited above with respect to claim 16. Additionally, claims 17 - 21 are allowable on their own merit because there is no suggestion, motivation, or teaching to combine or modify the teachings of Yuan and Baccelli to produce the subject matter in the claims. Claims 17-21, therefore, are allowable over the cited references for at least the reasons recited above. Applicants respectfully request withdrawal of the rejection of claims 16 - 21 over Yuan and Baccelli.

Claims 23-29 were rejected under 35 USC §103(a) as being allegedly unpatentable over U.S. Patent No. 5,616,142 to Yuan et al. in view of International Patent No. WO9801079 to Dall. Regarding independent claim 23, Applicants submit that a *prima facie* case of obviousness cannot be established because there is no proper teaching, suggestion or motivation to arrive at the combination of features recited in claim 23. The Office Action purports to provide motivation based on conclusory statements of generalized advantages by alleging that “[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to use the bone plate fasteners, as taught by Dall with the bone plate of Yuan such that it provides the ability to lock the fasteners to the plate and attach the plate to necessary boney structures.” This allegation was challenged in Applicants’ last response wherein Applicants stated that “[t]here is no

indication in the Office Action of why one of ordinary skill would decide to use Dall’s subject

RESPONSE TO FINAL OFFICE ACTION

Application Serial No. 10/775,388

Page 15 of 18

Atty. Docket No. 4002-3479

matter in Yuan.” After being so challenged, the Final Office Action added to the previous Office Action by alleging that “. . . the knowledge generally available to one of ordinary skill in the art would easily recognize that the bone fastener configuration Dall designed to fasten a bone plate to bone could be used to fasten the bone elements of Yuan et al to bone wherein the fastener configuration does not require different lengths and there is no longer any need to keep a range of bone screw for a surgeon’s use.” Page 3 [emphasis in original]. Applicants take note of the emphasis placed on the term “easily” which is used in a context to further allege that the prima facie case of obviousness has been met.

To establish a prima facie case of obviousness, however, the Office Action must first establish a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. MPEP 2143. A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made,” because the references relied upon teach that all aspects of the claimed invention were individually known in the art, is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. MPEP 2143.01 (IV). The Examiner’s use of the phrase “one of ordinary skill in the art would easily recognize” is equivalent to whether modifications are “well within the ordinary skill of the art at the time the claimed invention was made.”

Furthermore, it is believed that neither the Yuan reference nor the Dall reference explicitly disclose the motivation alleged in the Office Action, and no citation is provided that identifies where such motivation may be found. By failing to identify where the motivation can be found, or even an objective reason to combine the teachings of the references, the Office



Action fails to meet the *prima facie* case for obviousness. It appears, therefore, that the Office Action is possibly using impermissible hindsight to provide the requisite motivation; or alternatively, the Office Action is relying on facts within the personal knowledge of the Examiner. If, on further review, the Office Action indeed relies on such facts, Applicants hereby request an affidavit of the Examiner, pursuant to 37 C.F.R. 1.104(d)(2), to specifically describe such personal knowledge in order to better develop a full record on which the prosecution can advance.

Claims 24 - 29 depend from claim 16 and therefore include all of the elements of claim 23. Claims 24 - 29 are allowable over the cited reference for at least the reasons cited above with respect to claim 23. Additionally, claim 24 is allowable on its own merit because neither Yuan nor Dall disclose washers adapted to fit around at least part of at least one of said fasteners adjacent to at least one of said nuts. Yuan and Dall discloses on the other hand, devices that are used without washers. With specific regards to Dall, split ring element 16 is not a washer and is not used as a washer, as can be seen by the description of the use of split ring (pg. 5, lines 31 - 33) wherein the split ring, or a spring section or length of resilient wire bent to engage the thread in its unflexed shape and connects upper and lower parts of the housing. Claim 24, therefore, is allowable over the cited reference for at least the reasons recited above.

Additionally, claims 25 - 29 are allowable on its own merit because there is no suggestion, motivation, or teaching to combine or modify the teachings of Yuan and Dall to produce the subject matter in the claims. Claims 25 - 29, therefore, are allowable over the cited references for at least the reasons recited above. Applicants respectfully request withdrawal of the rejection of claims 23 - 29 over Yuan and Dall.

### CONCLUSION

Reconsideration in view of the above remarks is respectfully requested. All claims are allowable, and a Notice of Allowance is respectfully requested. Should it be determined that any further action is necessary to place this application in better form for allowance, or for appeal should that become necessary, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

By: Marta L. Puckett  
Marta L. Puckett, Reg. No. 57,256  
Woodard, Emhardt, Moriarty,  
McNett & Henry LLP  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
Telephone: (317) 634-3456

004002-003479.MTS.#408025